No. 15-274

IN THE

Supreme Court of the United States

WHOLE WOMAN'S HEALTH, ET AL.,

Petitioners,

v.

KIRK COLE, M.D., COMMISSIONER, TEXAS DEPARTMENT OF STATE HEALTH SERVICES, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF HEALTH ECONOMISTS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

PAGE

STATEMENT OF INTERESTS OF AMICI 1

INTRODUCTION 2

SUMMARY OF ARGUMENT 5

ARGUMENT 7

A. Amici's scholarship and work quantifies the benefits and burdens inherent in government regulation and has determined, especially in the medical context, that those burdens often exceed the benefits. 7

B. Courts should perform an evidence-based analysis to determine whether an abortion regulation imposes an undue burden 12

C. **The Fifth Circuit's decision cannot stand when applying an undue-burden test to abortion regulations because, even when applying rational-basis review, this Court and the Fifth Circuit have allowed the kind of evidentiary analysis the Fifth Circuit rejected below.** 14

CONCLUSION 18

TABLE OF AUTHORITIES

PAGE(S)

Federal Cases

City of Cleburne v. Cleburne Living Center, Inc.
473 U.S. 432 (1985) 16

Craigmiles v. Giles
312 F.3d 220 (6th Cir. 2002) 17

Kelo v. City of New London
545 U.S. 469 (2005) 15

Mazurek v. Armstrong
520 U.S. 968 (1997) 17, 18

Merrifield v. Lockyear
547 F.3d 978 (9th Cir. 2008) 17

Mugler v. Kansas
123 U.S. 623 (1887) 14, 15

N.C. State Bd. of Dental Exam'rs v. FTC
135 S.Ct. 1101 (2015) 8

Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott
748 F.3d 583 (5th Cir. 2014) 12, 16

Planned Parenthood of Se. Pa. v. Casey
505 U.S. 833 (1992) 6

Planned Parenthood of Wis., Inc. v. Schimel
No. 15-1736, 806 F.3d 908
(7th Cir. Nov. 23, 2015) 13

Plyler v. Doe
457 U.S. 202 (1982) 15

St. Joseph Abbey v. Castille
712 F.3d 215 (5th Cir. 2013) 16, 17

Whole Woman's Health v. Cole
790 F.3d 563 (5th Cir. 2015) 3, 12, 17

Federal Statutes

Regulatory Right to Know Act, Pub. L. No.
106-554, 114 Stat. 2763 (2001) 5

Other Federal Authorities

Exec. Order. No. 12,291
3 C.F.R. § 127 (1982) 5

Exec. Order. No. 12,498
3 C.F.R. § 323 (1986) 5

Exec. Order No. 12,866
3 C.F.R. § 1268 (1994) 5

Federal Trade Commission, Office of Policy Planning, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses* (Mar. 2014) 6, 8, 9

The White House, *Occupational Licensing: A Framework for Policymakers* (July 2015) 6

Other State Authorities

Texas Sunset Advisory Commission, *Sunset in Texas 2015-2017* 5, 10

Other Authorities

Robert W. Hahn, *Policy Watch: Government Analysis of the Benefits and Costs of Regulation*, J. ECON. PERSP., Fall 1998 5

Vivian Ho et al., *State Deregulation and Medicare Costs for Acute Cardiac Care*, 70 MED. CARE RES. AND REV. 185 (2013) 8, 9

Barbara Mark et al., *California's Minimum Nurse Staffing Legislation: Results from a Natural Experiment*, 48 HEALTH SERV. RES. 435 (2013) 10

Barbara Mark et al., *California's Minimum-Nurse-Staffing Regulations and Nurses' Wages* 28 HEALTH AFFAIRS w326-w334 (Feb. 10, 2009) 11

Dana B. Mukamel et al., *Does State Regulation of Quality Impose Costs on Nursing Homes*, 49 MED. CARE 529 (June 2011) 7, 11

Jack Needleman et al., *Nurse Staffing Levels and the Quality of Care in Hospitals*, 346 NEW ENG. J. MED. 1715 (2002) 10

Daniel Polsky et al., *The Effect of Entry Regulation in the Health-Care Sector: The Case of Home Health*, 110 J. OF PUB. ECON., Feb. 2014 11

Kevin Stange, *How Does Provider Supply and Regulation Influence Health Care Markets*, 33 J. of HEALTH ECON., Jan. 2014 11

STATEMENT OF INTERESTS OF AMICI[1]

Amici are economists who study the marketplace for health-care services as well as other marketplaces in the U.S. economy. They have an interest in ensuring that policy makers consider the full range of benefits and burdens regulations impose and in ensuring that those policy makers utilize a robust set of tools when making that assessment. They also have a policy and an academic interest in analyzing how the regulation of medical providers and services affects the cost and availability of health care. Amici work to quantify the burdens that result from regulating markets, including the market for health-care services. Amici believe that an evidence-based approach is the only way to make a meaningful assessment of either the burdens a regulation imposes or the benefits it confers.

Amici's interest in this matter is to ensure that courts, when deciding whether a given medical regulation unduly burdens the abortion right, use an observational, evidence-based methodology to weigh a regulation's burdens against its safety benefits. Amici's scholarship uses economic tools that rely on, among other sources, observational evidence to quantify regulatory benefits and burdens. Thus, Amici's work provides a useful framework for a court

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[1] No person or entity other than Amici and their counsel made a monetary contribution to the preparation or submission of this brief. No counsel to a party authored this brief in whole or in part. Petitioners and Respondents have consented to the filing of this brief, as reflected in letters filed with the Clerk of Court.

evaluating whether a regulation unduly burdens a patient's ability to obtain a particular medical procedure. Courts can use that framework to apply observational evidence in determining (i) whether a safety risk really exists, (ii) whether the regulation will ameliorate that risk, and to what degree; and (iii) the scope of the burden the regulation imposes. These determinations can aid a court in deciding whether a regulation's burden outweighs its benefit. Amici have an interest in this case because the Fifth Circuit's decision, by unduly limiting the manner in which courts can use observational evidence in assessing regulatory burdens and benefits, conflicts with the principle underlying Amici's scholarly work.

A complete list of Amici is provided in the Appendix to this Brief.

INTRODUCTION

Amici's scholarship has quantified both positive and negative effects that flow from regulation. Research applying Amici's methods have found that regulations—even those purportedly enacted to foster patient safety—can impose a significant burden—such as lost access to care—without any corresponding safety benefit. Thus, Amici believe that when deciding if a medical regulation unduly burdens a particular procedure, such as abortion, a court must engage in an evidentiary analysis of the regulation's safety benefits and corresponding burdens. By unduly limiting the district court's ability to use an empirical or evidence-based evaluation method, the Fifth Circuit effectively precluded any meaningful review

of whether the challenged regulation's burden on the abortion right was undue.

From Amici's perspective, the Fifth Circuit's approach is misguided because it restricts the district court from engaging in a robust empirical inquiry—one necessary to determining whether a regulation truly imposes an undue burden on the abortion right. First, the Fifth Circuit guts the purpose prong of the undue-burden standard by forcing lower courts to accept a policy maker's *stated* rationale for legislation and leaves little room for those courts to question or test that rationale. *See Whole Woman's Health v. Cole*, 790 F.3d 563, 584-586 (5th Cir. 2015). This renders the undue-burden standard's purpose prong toothless, because that prong is meaningless unless a court can apply some empirical check to evaluate the regulation's true purpose. Likewise, the Fifth Circuit, by sanctioning a regulation so long as the court can imagine any *conceivable* basis in which the regulation is related to a legitimate state interest regardless of whether that basis has any grounding in reality, eviscerates the rational-basis review inquiry. *Id.* at 587. Finally, the Fifth Circuit prevents lower courts from inquiring whether the regulation actually advances its stated purpose, even though such inquiry is necessary to determine whether the burden a regulation imposes is due *or* undue. *Id.* at 586.

Economics is a theoretic and empirical science; it encompasses analyzing policies by scrutinizing how they actually operate, what their actual effects are, and determining whether they actually achieve their stated goals. This sort of inquiry is critical to understanding and shaping policy outcomes. From Amici's technical viewpoint as economists, the Fifth

Circuit's approach is dangerous, because it restricts lower courts' ability to engage in this sort of empirical inquiry. It forces courts to rely on incomplete and speculative information that admittedly may have no basis in reality. This is dangerous for any sort of policy inquiry, but particularly when a constitutional right is at stake. The Fifth Circuit's decision allows a policy maker to simply claim that a regulation addresses a safety concern, and then use that claim to advance some other agenda, such as reducing access to abortion. Congress, Presidents, and courts have all recognized the risk that policy makers may provide a stated, permissible purpose for regulation as a pretext for some non-permitted, improper purpose, and each has enacted or ordered steps to counteract such pretextual regulation.

Amici are mindful that courts work scrupulously to respect separation of powers and to leave the difficult task of weighing evidence and competing policy goals to policy makers. Nevertheless, given that this Court *has* enunciated a particular test for evaluating abortion regulations, Amici urge the Court to ensure that test remains as robust as possible and reverse the limitations the Fifth Circuit has placed upon what should be an empirical inquiry.

Courts, when evaluating regulations, are perfectly capable of applying economic principles, such as those that Amici use. The Fifth Circuit and other courts have engaged in this kind of evaluation when deciding whether a regulation advances a public health or safety objective, even when applying rational-basis review to that evaluation. Amici therefore believe that that Fifth Circuit's decision

should be reversed, and that courts should be allowed to engage in an empirical investigation—including one that takes into account actual safety benefits and burdens—when evaluating abortion regulations.

SUMMARY OF ARGUMENT

Congress, successive Presidents of both political parties, and state governments have recognized the need for evidence-based impact review of regulations. *See, e.g.*, Regulatory Right to Know Act, Pub. L. No. 106-554, 114 Stat. 2763 (2001); Exec. Order. No. 12,291, 3 C.F.R. § 127 (1982) (requiring agencies to use cost-benefit analysis); Exec. Order. No. 12,498, 3 C.F.R. § 323 (1986) (requiring agencies to prepare annual regulatory plan and adhere to cost-benefit principles); Exec. Order No. 12,866, 3 C.F.R. § 1268 (1994) (requiring agencies to assess all costs and benefits of regulatory alternatives). At the state level, Texas's own Sunset Commission, which was founded in 1977, pioneered periodic review of regulatory agencies to "look at every aspect of a program to ensure regulation is serving a needed purpose." Texas Sunset Advisory Commission, *Sunset in Texas 2015-2017* (hereinafter, "Sunset Report")[2]; *see also* Robert W. Hahn, *Policy Watch: Government Analysis of the Benefits and Costs of Regulation*, J. ECON. PERSP., Fall 1998, at 201. This long-term trend toward rigorous cost-benefit analysis of regulations has recently included medical and

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[2] Available at https://www.sunset.texas.gov/public/uploads/files/reports/Sunset%20in%20Texas_0.pdf

health professions. For example, the Federal Trade Commission staff has reported that states should apply an evidentiary, quantitative approach in evaluating whether nursing regulations serve their purported public-safety purpose. *See* Federal Trade Commission, Office of Policy Planning, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses* (Mar. 2014) (hereinafter "FTC Report").[3] A recent executive branch study encompassing input from the Department of Treasury, the Council of Economic Advisers, and the Department of Labor has reported the need for such scrutiny in occupational licensing generally. *See* The White House, *Occupational Licensing: A Framework for Policymakers* (July 2015).[4]

Amici understand that under governing precedent courts faced with a challenge to an abortion regulation must evaluate whether that regulation imposes an undue burden on the abortion right. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 877 (1992). If courts must evaluate whether a regulatory burden is undue, then the *policy-making* principle described above, *i.e.*, using evidence in determining if a regulatory need exists and in determining if a regulation addresses that need—applies equally as a principle of *judicial* decision making. At a minimum, from Amici's

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[3] Available at https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses

[4] Available at https://www.whitehouse.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf

viewpoint, there is a no way to assess undue burden without examining evidence of whether a regulation's claimed safety purpose is advanced. Moreover, courts have historically applied evidence-based analysis to weigh regulatory burdens against benefits, when required. They can do so here, and for this reason, Amici believe the Fifth Circuit's decision, which restricts such evaluation, should be reversed.

ARGUMENT

A. Amici's scholarship and work quantifies the benefits and burdens inherent in government regulation and has determined, especially in the medical context, that those burdens often exceed the benefits.

"Government regulation of private industry" aims to shape industry participants' behavior in "quality, safety, fairness, or competition." Dana B. Mukamel et al., *Does State Regulation of Quality Impose Costs on Nursing Homes*, 49 MED. CARE 529 (June 2011). Such regulation necessarily entails costs—

> both "direct" costs, which arise from activities undertaken by firms in the regulated industry to meet the standards, and "indirect" costs, which arise from the activities of regulatory agencies to develop, implement, and monitor compliance with the standards and from the activities of the regulated firms to demonstrate compliance.

Id. Thus, in evaluating a regulation, it is important to examine the objective, *e.g.*, safety, quality, fairness, or competition. As scholars in Amici's field have concluded, the cost of certain regulations, including regulations themselves aimed at reducing costs, often exceed those regulations' benefits. *See, e.g.*, Vivian Ho et al., *State Deregulation and Medicare Costs for Acute Cardiac Care*, 70 MED. CARE RES. AND REV. 185 (2013) (imposition of "certificate of need" requirement before administering coronary artery bypass surgery failed to improve patient outcomes but imposed costs that exceeded any savings generated by reduction in surgeries performed).

Moreover, as the FTC staff observed in a recently published report involving regulation of advanced practice nurse practitioners (APNPs), it is important to examine the "countervailing benefits" that a safety regulation provides, against the burdens it imposes. FTC Report at 4 & 19. The report addressed regulations relating to supervision, by licensed physicians, of APNPs. It determined that the very need for regulation should be determined based on evidence rather than speculation: "[I]t may be important to scrutinize relevant safety and quality evidence to determine *whether or where legitimate safety concerns exist.*" *Id.* at 4. (emphasis added). So, for example, before regulating nurse practitioners' ability to provide a particular kind of diagnostic test, the FTC staff suggests an evidentiary assessment of whether their doing so presents any safety risk that warrants regulation. Evidence-based regulation reduces the risk that the regulation will serve some other purpose, such restricting competition or access to a procedure. *Cf. N.C. State Bd. of Dental Exam'rs*

v. FTC, 135 S.Ct. 1101, 1111 (2015) (noting the risk of pretextual regulation because even "established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern").

The FTC report further concluded that even where evidence supports the need for regulation in a particular area, the regulation should be

> narrowly tailored to address *well founded* health and safety concerns, and should not be more restrictive than patient protection requires. Otherwise, such limits can deny health care consumers the benefits of competition, without providing significant countervailing benefits.

FTC Report at 4 (emphasis added). It highlighted the need to go beyond a 10,000-foot level question of whether some safety concern could theoretically exist. Instead, the report calls for scrutinizing whether a particular regulation (*e.g.*, a regulation regarding APNPs' ability to administer diagnostic tests) is tied to a legitimate safety concern and whether the regulation helps ameliorate that safety risk. *Id.* at 4 ("[S]crutiny can be applied not just to the general question whether the State requires physician supervision . . . but to the particular terms of those requirements as they are."). In the parlance of Amici's work, the report calls for examining whether regulation is necessary to effect a particular behavior in a private industry. The report advocates for doing this by looking at both a regulation's cost and at the degree to which the regulation accomplishes its stated purpose. This inquiry ensures

that the cost, *e.g.*, loss of competitive providers, offers some "countervailing benefits," *e.g.*, quantifiable safety improvement.

The FTC staff report's conclusion is strikingly similar to Texas's own policy regarding regulation, including occupational regulation across professions. Texas's Sunset Commission, which was formed in 1977 at the vanguard of the deregulation movement, periodically reviews the very existence of regulatory agencies to determine whether their function remains necessary and, if so, whether the agency is performing that function in the least burdensome way possible. *See* Sunset Report at 4 (requiring periodic review of whether an agency's "occupational licensing program serve[s] a meaningful public interest and provide[s] the least restrictive form of regulation needed to protect the public interest"). The Sunset Commission, which is not just created by the Texas Legislature but actually comprises numerous legislators, has also explained the purpose that its regulatory reviews serve: "Sunset looks at every aspect of a program to ensure regulation is serving a needed purpose and regulatory agencies conduct their business with fairness, impartiality, and transparency to the public and regulated groups." Sunset Report at 9.

Amici's scholarship and work provide a way to use traditional economic analysis tools to determine the necessity for regulation, and a regulation's costs and benefits. It looks at all the variables relevant to a regulatory need and attempts to quantify them. Moreover, unlike more speculative approaches, these analyses can be recreated and tested for validity. So, for example, Amici may try to quantify the safety or

risk factors associated with a particular activity in the medical field. *See, e.g.*, Jack Needleman et al., *Nurse Staffing Levels and the Quality of Care in Hospitals*, 346 NEW ENG. J. MED. 1715 (2002). As an example, Amici may look at the frequency of particular negative outcomes from a particular kind of procedure or activity. *See, e.g.*, Barbara Mark et al., *California's Minimum Nurse Staffing Legislation: Results from a Natural Experiment*, 48 HEALTH SERV. RES. 435 (2013). Amici may then look at a regulation aimed to address that safety or risk factor and evaluate that regulation costs. *See, e.g.*, Barbara Mark, et al., *California's Minimum-Nurse-Staffing Regulations and Nurses' Wages*, 28 HEALTH AFFAIRS w326-w334 (Feb. 10, 2009).[5] Finally, Amici may try to correlate improvements in safety to the regulatory costs. Thus, Amici can use case-specific data to assist a decision maker in measuring the "positive" effects of regulation and balancing that effect against its costs. *See, e.g.*, Daniel Polsky et al., *The Effect of Entry Regulation in the Health-Care Sector: The Case of Home Health*, 110 J. OF PUB. ECON., Feb. 2014 at 1 (quantifying the effects of a particular home-health regulation—certificate of need laws—and correlating that regulation's presence or absence to specific cost and quality measures); Dana B. Mukamel et al., *Does State Regulation of Quality Impose Costs on Nursing Homes*, 49 MED. CARE 532 (2011) (quantifying stringency of state nursing home regulation and correlating stringency to care deficiencies); Kevin Stange, *How Does Provider Supply and Regulation*

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[5] Available at http://content.healthaffairs.org/content/28/2/w326.full.pdf+html

Influence Health Care Markets, 33 J. of HEALTH ECON., Jan. 2014, at 1 (applying a quantitative, empirical approach to analyzing the effect of regulations on nurse practitioners and physician's assistants on utilization of services).

B. Courts should perform an evidence-based analysis to determine whether an abortion regulation imposes an undue burden.

The Fifth Circuit's decision is irreconcilable with this Court's precedent, which Amici understand to prohibit unduly burdening a woman's right to pre-viability abortion. From Amici's perspective as economists who analyze regulations' costs and benefits in health-care services markets, there is no way for a court or any other decision maker to determine whether the burden a regulation imposes is undue unless the court performs an evidence-based analysis. Thus, Amici believe that when the Fifth Circuit held an abortion restriction must be sustained if "any conceivable rationale exists" for its enactment, it eviscerated this Court's prohibition on undue restrictions of abortion. 790 F.3d at 587 (quoting *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 748 F.3d 583, 594 (5th Cir. 2014), *reh'g en banc denied*, 769 F.3d 330 (5th Cir. 2014). Indeed, even though the district court as fact finder had found that the regulations did nothing to advance women's health and safety, 790 F.3d at 579, the Fifth Circuit found that Texas had met its burden of showing that the challenged regulation did not unduly burden the abortion right.

Permitting a legislature to regulate abortion based on nothing more than speculation creates the risk that the legislature may use safety as a pretext to enact a regulation actually aimed at accomplishing a non-permissible objective, such as restricting access to abortion services. As the Seventh Circuit recently recognized, persons opposed to abortion rights may choose to advance their objectives "indirectly, seeking to discourage abortions by making it more difficult for women to obtain them." *Planned Parenthood of Wis., Inc. v. Schimel*, No. 15-1736, 806 F.3d 908, slip op., at 25 (7th Cir. Nov. 23, 2015). The Seventh Circuit even highlighted the concern that abortion opponents "may do this in the name of protecting the health of women who have abortions, yet as in this case the specific measures they support may do little or nothing for health, but rather strew impediments to abortion." *Id.* Amici believe that, in order to ensure that safety does not become a pretext for regulation with an improper objective, courts must have the ability to test the regulation's accomplishment of the stated safety objective by using empirical evidence.

For these reasons, Amici believe the Fifth Circuit's decision should be reversed. So long as state legislatures may not unduly burden a woman's right to abortion, courts must have the ability to use empirical evidence when reviewing whether the regulation imposes an undue burden. Amici are not suggesting that this Court prescribe economic-impact analysis as the only way to determine whether a regulation unduly burdens the abortion right. However, economic-impact analysis is an important tool that courts may use when undertaking the undue-burden inquiry. Using economic-impact analysis when evaluating regulatory burdens and

benefits follows the approach set out in FTC staff and executive agencies' reports, as well as Texas's own long-standing practice of Sunset Commission review.

C. The Fifth Circuit's decision cannot stand when applying an undue-burden test to abortion regulations because, even when applying rational-basis review, this Court and the Fifth Circuit have allowed the kind of evidentiary analysis the Fifth Circuit rejected below.[6]

The Fifth Circuit's approach flies in the face of precedent establishing that even under rational-basis review, courts *are* permitted to inquire whether a regulation advances its stated purpose. Moreover, requiring such evidence-based analysis is the only way to reconcile rational-basis review with the ban on unduly burdening abortion rights.

In the first articulation of rational-basis review in *Mugler v. Kansas*, 123 U.S. 623 (1887), this Court established its competence and willingness to determine whether legislation advances its stated purpose in holding that, while "every possible

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[6] Amici refer the Court to the discussion of the proper level of scrutiny applied to abortion regulations that is set forth in Petitioner's Brief, at pages 44-48. Amici provide this section to demonstrate that regardless of the level of scrutiny applied, Courts have permitted an evidence-based analysis of whether a regulation has a meaningful relationship to its intended purpose.

presumption is to be indulged in favor of the validity of a statute," the presumption is rebuttable: "If a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, *has no real or substantial relation to those objects*, or is a palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the constitution." *Id.* at 661 (emphasis added).

More recently, the Court has repeatedly scrutinized legislative enactments to determine whether they advance their stated purpose, even when applying the rational-basis review standard. In *Kelo v. City of New London*, this Court stated that a municipality would not "be allowed to take property under the mere pretext of a public purpose, when its actual purpose was to bestow a private benefit." 545 U.S. 469, 478 (2005). Justice Kennedy's concurring opinion noted that

> [a] court applying rational-basis review under the Public Use Clause should strike down a taking that, by a clear showing, is intended to favor a particular private party, with only incidental or pretextual public benefits, just as a court applying rational-basis review under the Equal Protection Clause must strike down a government classification that is clearly intended to injure a particular class of private parties, with only incidental or pretextual public justifications.

Id. at 491. Likewise, in *Plyler v. Doe*, the Court held that in deciding whether a state policy to deny undocumented immigrant children free public education passed constitutional muster, the Court inquired whether a "substantial state interest" was advanced by examining the evidentiary record—not simply hypothesizing whether some possible state interest may be advanced by the enactment. *See* 457 U.S. 202, 230 (1982). *See also id.* at 228 ("There is no evidence *in the record* suggesting that illegal entrants impose any significant burden on the State's economy. To the contrary, the available evidence suggests that illegal aliens underutilize public services, while contributing their labor to the local economy and tax money to the state fisc.") (emphasis added). And, the Court applied a similar approach in *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 450-51 (1985). There, this Court invalidated a city ordinance requiring a special permit for housing facilities serving mentally disabled persons, where the evidence did not support city's claimed justification for special regulations applicable to housing for the mentally disabled. *Id.*

The Fifth Circuit itself has shown no hesitation in scrutinizing the record evidence to determine whether legislation actually advances its purported health and safety objectives. Notwithstanding the fact the Fifth Circuit has explicitly stated that "rational basis review" is not "empirical basis review" when it comes to abortion regulation, *see Planned Parenthood of Greater Texas*, 748 F.3d at 596, it has not taken that approach with other kinds of regulation. In *St. Joseph Abbey v. Castille*, 712 F.3d 215, 226-27 (5th Cir. 2013), the court invalidated a Louisiana law that barred anyone

other than state-licensed funeral directors at state-licensed funeral homes from engaging in intrastate casket sales. In reaching its decision, on equal protection and due process grounds, the Fifth Circuit expressly looked at whether the record showed that the law advanced its purported objective of protecting consumers and advancing public health and safety. Not finding any *evidence* that the law accomplished those objectives, the Fifth Circuit affirmed the district court's decision to invalidate the law. It explained: "The great deference due state economic regulation does not demand judicial blindness to the history of a challenged rule or the context of its adoption or does it require courts to accept nonsensical explanations for regulation." *Id.* at 226; *accord Merrifield v. Lockyear*, 547 F.3d 978 (9th Cir. 2008) (striking down pest-control occupational licensing requirement); *Craigmiles v. Giles*, 312 F.3d 220 (6th Cir. 2002) (striking down casket-sale regulations). *St. Joseph Abbey* contrasts starkly with the Fifth Circuit's decision here, where it prohibited even inquiring to the kind of evidence that led to invalidating the regulation at issue in *St. Joseph Abbey*. *Compare St. Joseph Abbey*, 712 F.3d at 223-227 *with Whole Woman's Health*, 790 F.3d at 584-588.

Notably, this Court's prior decision in *Mazurek v. Armstrong*, 520 U.S. 968 (1997), does not preclude the kind of evidence-based analysis that Amici favor. *Mazurek* involved a challenge to a Montana law requiring that only licensed physicians could perform abortions. *Id.* at 970. The Ninth Circuit invalidated the law based on a conclusion that the Montana Legislature had passed the law to advance an improper purpose, *i.e.*, restricting access to abortion

services. *Id.* at 972. This Court reversed the Ninth Circuit on the narrow ground that the record did not have any evidence to support the conclusion that the law had the purpose or effect of unduly burdening the abortion right. *Id.* at 972. This Court relied on the record evidence that the Montana law only affected one non-physician provider. *Id.* at 973. It further relied on evidence that even before the enactment, a physician had to supervise the non-physician provider, further suggesting that the law did not curtail access in light of the particular facts on the ground in Montana. To the extent it has any relevance here, *Mazurek* actually favors reversing the Fifth Circuit's decision, because *Mazurek* relies on record *evidence* regarding the statute's purpose and effects—the very kind of evidence that the Fifth Circuit said the district court could not consider.

CONCLUSION

For the reasons stated, Amici respectfully request that this Court reverse the judgment of the Fifth Circuit Court of Appeals.

Respectfully submitted,

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APPENDIX
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